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21 CFR Ch. I (4–1–05 Edition)

(a) As a wetting agent in the following fumaric acid-acidulated foods: Dry gelatin dessert, dry beverage base, and fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry gelatin dessert and dry beverage base shall bear adequate directions for use, and the additive shall be used in such an amount that the finished gelatin dessert will contain not in excess of 15 parts per million of the additive and the finished beverage or fruit juice drink will contain not in excess of 10 parts per million of the additive.

(b) As a processing aid in sugar factories in the production of unrefined cane sugar, in an amount not in excess of 0.5 part per million of the additive per percentage point of sucrose in the juice, syrup, or massecuite being processed, and so used that the final molasses will contain no more than 25 parts per million of the additive.

(c) As a solubilizing agent on gums and hydrophilic colloids to be used in food as stabilizing and thickening agents, when standards of identity do not preclude such use. The additive is used in an amount not to exceed 0.5 percent by weight of the gums or hydrophilic colloids.

(d) As an emulsifying agent for cocoa fat in noncarbonated beverages containing cocoa, whereby the amount of the additive does not exceed 25 parts per million of the finished beverage.

(e) As a dispersing agent in “cocoa with dioctyl sodium sulfosuccinate for manufacturing” that conforms to the provisions of § 163.117 of this chapter and the use limitations prescribed in § 172.520, in an amount not to exceed 0.4 percent by weight thereof.

(f) As a processing aid and wetting agent in combination with α -hydro-*omega*-hydroxy - poly(oxyethylene) - poly(oxypropylene) (53–59 moles) poly(oxyethylene) (14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9 °C–12 °C in 10 percent aqueous solution, for fumaric acid used in fumaric acid-acidulated dry beverage base and in fumaric acid-acidulated fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry beverage base shall bear adequate directions for use, and the addi-

tives shall be used in such an amount that the finished beverage or fruit juice drink will contain not in excess of a total of 10 parts per million of the dioctyl sodium sulfosuccinate-block copolymer combination.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.811 Glyceryl tristearate.

The food additive glyceryl tristearate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive (CAS Reg. No. 555-43-1) is prepared by reacting stearic acid with glycerol in the presence of a suitable catalyst.

(b) The food additive meets the following specifications:

Acid number: Not to exceed 1.0.
Iodine number: Not to exceed 1.0.
Saponification number: 186–192.
Hydroxyl number: Not to exceed 5.0.
Free glycerol content: Not to exceed 0.5 percent.
Unsaponifiable matter: Not to exceed 0.5 percent.
Melting point (Class II): 69 °C–73 °C.

(c) The additive is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

Uses	Limitations
1. As a crystallization accelerator in cocoa products, in imitation chocolate, and in compound coatings.	Not to exceed 1 percent of the combined weight of the formulation.
2. As a formulation aid as defined in § 170.3(o)(14) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, and surface-finishing agent as defined in § 170.3(o)(30) of this chapter in food.	Not to exceed 0.5 percent.
3. As a formulation aid as defined in § 170.3(o)(14) of this chapter in confections.	Not to exceed 3.0 percent of the combined weight of the formulation.
4. As a formulation aid as defined in § 170.3(o)(14) of this chapter in fats and oils as defined in § 170.3 (n)(12) of this chapter.	Not to exceed 1.0 percent of the combined weight of the formulation.
5. As a winterization and fractionation aid in fat and oil processing.	Not to exceed 0.5 percent by weight of the processed fat or oil.

(d) To assure safe use of the additive:

(1) In addition to the other information required by the act, the label or labeling of the additive shall bear the name of the additive.

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(2) The label of the additive shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[53 FR 21632, June 9, 1988, as amended at 59 FR 24924, May 13, 1994]

§ 172.812 Glycine.

The food additive glycine may be safely used for technological purposes in food in accordance with the following prescribed conditions:

(a) The additive complies with the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 140, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) The additive is used or intended for use as follows:

Uses	Limitations
As a masking agent for the bitter aftertaste of saccharin used in manufactured beverages and beverage bases.	Not to exceed 0.2 percent in the finished beverage.
As a stabilizer in mono- and diglycerides prepared by the glycerolysis of edible fats or oils.	Not to exceed 0.02 percent of the mono- and diglycerides.

(c) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The labeling of the additive shall bear adequate directions for use of the additive in compliance with the provisions of this section.

(2) The labeling of beverage bases containing the additive shall bear adequate directions for use to provide that beverages prepared therefrom shall contain no more than 0.2 percent glycine.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.814 Hydroxylated lecithin.

The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, "hydroxylated lecithin".

(2) Adequate directions for its use.

§ 172.816 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

Acid number: 10-20
Hydroxyl number: 200-300
pH (5% aqueous): 4.8-5.0
Saponification number: 178-190

(b) It is used or intended for use as follows:

(1) As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.

(2) As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions: